REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Title of the Invention:

The original TITLE of the invention was the result of a poor translation from German to English. Applicant respectfully requests that the TITLE be corrected to a more accurate translation in the instant application.

Specification:

The Examiner objected to the ABSTRACT of the invention because it exceeded 150 words in length. The ABSTRACT has been amended to bring its length into compliance with MPEP \$608.01(b). Applicant respectfully requests that the objection be removed.

Claim Status

Claims 1, 8, and 12 were amended. Claims 1-20 are pending. No new matter was added.

Double Patenting Rejection

Claims 1, 3-10, and 12-20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting

as being unpatentable over claims 1-10 and 12-20 of copending Application No. 10/588,695. Applicant traverses.

Applicant must point out to the Examiner that the test methods for determination of the ultrafiltration rates in albumin solution are different for the two applications. membranes addressed in copending Application No. 10/588,695 disclose a filtrate flow rate of $Q_F = 30 \text{ ml/(min·m}^2)$ through the membrane wall of a high-flux membrane is set in the ultrafiltration test. (Page 20, Lines 23-24). This is in contrast to the instant application wherein the filtrate flow rate is $Q_F = 10 \text{ ml/}(\text{min} \cdot \text{m}^2)$ through the membrane wall of a lowflux and/or middle-flux membrane in the ultrafiltration test. (Page 24, Lines 5-7). Despite the obvious difference between the testing methods, Applicant has amended the language of both claim 1 and claim 12 to read "5 to 23.5 $ml/(h \cdot m^2 \cdot mmHg)$ ". This amendment removes any possible overlap of ranges between the currently pending application and copending Application No. 10/588,695. (See M.P.E.P §2144.05) In light of this amendment, Applicant requests that the Examiner remove the provisional rejection of claims 1, 3-10, and 12-20 and the claims be allowed.

§102 Claim Rejections

Claims 1, 9, and 11 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,290,448 (hereinafter Sluma). Applicant traverses.

To anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); In re Marshall, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on PCT Article 33(3). See Titanium Metals Corp. v. Banner, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

Sluma does not disclose a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification.

Instead, Sluma discloses a membrane for dialysis composed of a hydrophobic polymer, polyacrylonitrile. The hollow fiber membranes of the instant invention are hydrophilic and are characterized by the absence of an additive that stabilizes

the pores in the membrane wall. After prior drying, the hollow fiber membranes of the instant invention have a sieving coefficient for albumin SC_{Alb} with a maximum value of 0.005, combined with a sieving coefficient for cytochrome c, SC_{CC} , that satisfies the equation:

$$SC_{CC} \ge 5 \cdot 10^{-5} \cdot UFR_{Alb}^{3} - 0.004 \cdot UFR_{Alb}^{2} + 0.1081 \cdot UFR_{Alb} - 0.25$$

On account of their hydrophilic properties, the hollow fiber membranes of the instant invention remain wettable with water, or other aqueous media, even after drying.

The membranes disclosed in Sluma, most particularly the membranes disclosed in the examples of Sluma, are treated by a softener bath consisting of a mixture of glycerol and water prior to being dried (Sluma, Column 3, Lines 36-39, Column 4, Lines 11-14). Thus, the sieving coefficients and the ultrafiltration rates disclosed in Sluma were obtained for hydrophobic membranes whose pore structure had been stabilized by glycerol (an additive stabilizing the pores in the membrane wall and after prior drying). Sluma's use of glycerol directly contradicts the language of claim 1 which requires "the absence of additives stabilizing the pores in the membrane wall and after prior drying". Therefore, the hollow fiber membranes of Sluma do not fulfill the criteria of claim 1 of the instant application.

The membranes of the instant invention allow excellent elimination of low molecular proteins and at the same time excellent retention of albumin, without the need for pore stabilization by post-treatment of the membranes with a liquid pore stabilizer glycerol or polyethylene glycol. (Specification, Page 11, Lines 4-12). The membranes of the instant invention retain the separation properties described above after drying even if they were not treated with a glycerol solution after extraction and before drying and/or are free from additives that stabilize the pores in the membrane wall. Additionally, the combination of a low sieving coefficient for albumin SCAlb with a high sieving coefficient for cytochrome c are unexpectedly obtained for the membranes of the instant invention without stabilization of the pores of the membranes. As stated above, Sluma does not disclose a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 1.

Accordingly, Sluma does not disclose all of the elements of claim 1. Therefore, this rejection must fail.

In reference to claims 9 and 11, "[I]f an independent claim is not anticipated by prior art, then its dependent

claims, which necessarily include the limitations of the independent claim, are not anticipated either. Kovin Assoc. v. Extech/Exterior Technologies, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 9 and 11 are not unpatentable over Sluma and should be allowed.

Claims 2 stands rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,290,448 (hereinafter Sluma) as evidenced by U.S. Patent No. 5,505,859 (hereinafter Dunweg). Applicant traverses.

Again, to anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim.

See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); In re Marshall, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on PCT Article 33(3). See Titanium Metals Corp. v. Banner, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

The above comments regarding Sluma are incorporated herein. As stated above, Sluma does not disclose a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 1 or claim 2. The Examiner then attempts to rely on Dunweg as disclosing a hollow fiber membrane according to claim 2, characterized in that it has a sieving coefficient for cytrochrome c that satisfies the relation

$$SC_{CC} \ge 5 \cdot 10^{-5} \cdot UFR_{Alb}^{3} - 0.004 \cdot UFR_{Alb}^{2} + 0.1081 \cdot UFR_{Alb} - 0.12$$
.

This could not be further from the truth. Dunweg does not disclose a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 2. On the contrary, Dunweg relates to dialysis membranes made from regenerated cellulose polymer (Dunweg, Column 3, Lines 29-31). This is contrary to claim 2 of the instant invention which discloses the use of a synthetic first polymer. The instant application makes a distinct differentiation between cellulosic polymers and synthetic polymers. (Specification, Page 2, Lines 18-26).

There is no disclosure in Dunweg's Example 3 of a membrane structure as required according to claim 2. Specifically, there is no disclosure of an integrally asymmetric structure of the hollow fiber membrane having a porous separating layer on the inner surface facing the lumen of the hollow fiber membrane. Additionally, the membrane of Dunweg's Example 3 does not possess the claimed sharp separation characteristic with a sieving coefficient for albumin, SC_{Alb}, with a maximum value of 0.005, combined with a sieving coefficient for cytochrome c, SC_{CC}, that satisfies the equation:

$$SC_{CC} \ge 5 \cdot 10^{-5} \cdot UFR_{Alb}^3 - 0.004 \cdot UFR_{Alb}^2 + 0.1081 \cdot UFR_{Alb} - 0.12$$

Even though the sieving coefficient for cytochrome c, SC_{CC} , being 0.88 for the membrane of example 3, fulfils the above equation taking into account an ultrafiltration rate in albumin solution of about 0.6 ml/($h \cdot m^2 \cdot mmHg$), the sieving coefficient for albumin, SC_{Alb} , is 0.08 and is by more than an order of magnitude higher that the upper limit according to claim 2 of the instant invention.

Additionally, the membranes disclosed in Dunweg, most particularly the membranes disclosed in examples 2 and 3 of Dunweg (example 3 refers to example 2), just like the membrane disclosed in the examples in Sluma, are treated by a mixture

of glycerol, isopropanol, and water prior to being dried

(Dunweg, Column 6, Lines 48-50). Thus, the sieving

coefficients and the ultrafiltration rates disclosed in Dunweg

were obtained for hydrophobic membranes whose pore structure

had been stabilized by glycerol (an additive stabilizing the

pores in the membrane wall and after prior drying). Dunweg's

use of glycerol directly contradicts the language of claim 1

which requires "the absence of additives stabilizing the pores

in the membrane wall and after prior drying". Therefore, the

hollow fiber membranes of Dunweg do not fulfill the criteria

of claim 2 of the instant application. As stated above,

Dunweg does not disclose a hydrophilic, water-wettable, semi
permeable hollow fiber membrane for blood purification in the

absence of additives stabilizing the pores in the membrane

wall and after prior drying as disclosed in claim 2.

Accordingly, Dunweg does not disclose all of the elements of claim 2. Therefore, this rejection must fail.

§103 Claim Rejections

Claims 3-8 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,290,448 (hereinafter Sluma) in view of U.S. Patent No. 4,906,375 (hereinafter Heilmann). Applicant traverses.

The above comments regarding Sluma are incorporated herein. As stated above, Sluma does not disclose a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 1. More specifically, Sluma does not disclose a hydrophilic hollow fiber membrane having an integrally asymmetric structure across its wall which in the absence of additive that stabilized the pores in the membrane wall, and after prior drying, have a sieving coefficient for SCALD, with a maximum value of 0.005, combined with a sieving coefficient for cytochrome c, SCCCC, that satisfies the equation:

$$SC_{CC} \ge 5 \cdot 10^{-5} \cdot UFR_{Alb}^{3} - 0.004 \cdot UFR_{Alb}^{2} + 0.1081 \cdot UFR_{Alb} - 0.25$$

The Examiner has rejected claim 3 as unpatentable under 35 U.S.C. 103 based on Sluma in view of Heilmann. The Examiner claims to have established a prima facie case of obviousness against the instant application. MPEP § 2143 "Basic Requirements of a *Prima Facie* Case of Obviousness" states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art

reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicant contends that none of the prior art references, neither Sluma, nor Heilmann, alone or in combination, teach, suggest, or provide a motivation for making a hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying with all of the claim elements of claim 3.

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See In re Zurko, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); In re Wilson, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the

information detailed above, it is clear that Sluma and Heilmann fail to teach or suggest all the limitations of Applicant's claims.

Regarding the first and second criterion, the Examiner's claim that Sluma and Heilmann are analogous art because they are from the same field of endeavor could not be further from the truth. There is no motivation for one or ordinary skill to modify the hollow fiber membrane disclosed in Sluma to include the hydrophilic polymers disclosed in Heilmann. Heilmann actually teaches away from the membranes disclosed in claim 1 of the instant application because the membranes disclosed in Heilmann lack the separation characteristics required by claim 1 of the instant application. See MPEP 2145(X)(D)(II)(It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983) (The claimed catalyst which contained both iron and an alkali metal was not suggested by the combination of a reference which taught the interchangeability of antimony and alkali metal with the same beneficial result, combined with a reference expressly excluding antimony from, and adding iron to, a catalyst.).

Looking to the example in Heilmann containing data on sieving coefficients for the hollow fiber membrane, for

myoglobin, a low molecular protein having a molecular weight similar to cytochrome c, a sieving coefficient was obtained between 0.5 and 0.6. The membrane in Heilmann has an ultrafiltration rate in water of about 210 ml/(h·m²·mmHg). (Heilmann, Page 10, Lines 15-22). Thus for the ultrafiltration rate in albumin solution, a value of approximately 20 ml/(h·m²·mmHg) can be derived. Entering the above data into the equation of claim 1 of the instant invention yields a value of 0.71. Thus, the values obtained by Heilmann are less than the values required according to claim 1 of the instant invention (no reasonable expectation of success). Therefore, one of ordinary skill in the art would not be motivated to combine the teachings of Sluma with the teachings of Heilmann.

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. KSR Int'l Co. v. Teleflex, Inc. 127 S.Ct 1727, 1741 (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Id.

The Court held that the TSM test must be applied flexibly, and take into account a number of factors "in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." Id. at 1740-41. Despite this flexibility, however, the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does." Id. "To facilitate review, this analysis should be made explicit." Id.

The obviousness rationale addressed in KSR was premised on combining elements known in the prior art. Id. at 1738-39. A parallel analysis applies, however, to a rejection premised on the obviousness of modifying a known composition to change its properties.

The KSR Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." Id. at 1741. See also Ex parte Thomas J. Whalen II, et al, BPAI 2007-4423 (2008).

Based on KSR v. Teleflex, Inc. 127 S.Ct. 1727, 167 L.Ed2d 705, 2007 U.S. Lexis 4745 (2007), the obviousness question may be broken down to: Is the invention predictable based upon the prior art? Id. at 1740, 721.

Simply, the answer to that question is "no." Hindsight reconstruction is not permitted as the Federal Circuit has repeatedly warned that the requisite motivation to modify a reference must come from the prior art, not Applicant's specification. See In re Dow Chem. Co., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-32 (Fed. Cir. 1988) ("there must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure.") Using an Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated piece of the prior art contravenes the statutory mandate of section 103 of judging obviousness at the point in time when the invention was made. See Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Only hindsight reconstruction based upon the instant specification would lead the Examiner to the conclusion that the claims in the instant application are rejected under §103 as unpatentable over Sluma in view of Heilmann. Accordingly, the instant rejection must be removed.

In reference to claims 4-8, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); In re Abele, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also In re Sernaker, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 4-8 are not unpatentable over Sluma in view of Heilmann and should be allowed.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,290,448 (hereinafter Sluma) in view of U.S. Patent No. 5,476,715 (hereinafter Otto).

Applicant traverses.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103(a), the reference or combination of references must teach or suggest all the elements of the claim (See MPEP 2143 above for the basic requirements of a prima facie case of obviousness). In this case, as shown below, Sluma in view of Otto does not teach all the elements of claim 10.

The above comments regarding Sluma are incorporated herein. As stated above, Sluma does not disclose a

hydrophilic, water-wettable, semi-permeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 1. The Examiner then attempts to rely on Otto as disclosing a polyelectrolyte with negative fixed charges that is physically bound in the separating layer. The Examiner's reliance on Otto is unfortunately misplaced.

Otto does not relate in any way to membranes, let alone to the separation characteristics of semipermeable membranes as disclosed in claims 1 and 10 of the instant invention. the contrary, Otto discloses the use of absorbent materials used to remove LDL and endotoxins from blood. (Otto, Column 4, Lines 27-32). The absorbent consists of spherical, unaggregated particles of polymeric acrylic acid, methacrylic acid, or acrylamide, having a particle size in the range of 50 to 250 µm and having spacers covalently bonded to the particles and organic ligands covalently bonded to the spacers. (Otto, Column 4, Lines 39-47). No hint is provided within either Otto or Sluma on how to modify the skin layer of the membrane disclosed in Sluma in order to improve the separation characteristics of that membrane. Again, hindsight reconstruction is not permitted as the Federal Circuit has repeatedly warned that the requisite motivation to modify a reference must come from the prior art, not Applicant's

specification. See In re Dow Chem. Co., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-32 (Fed. Cir. 1988). As stated above, Sluma does not disclose a hydrophilic, water-wettable, semipermeable hollow fiber membrane for blood purification in the absence of additives stabilizing the pores in the membrane wall and after prior drying as disclosed in claim 1 and Otto does not relate in any way to membranes, let alone to the separation characteristics of semipermeable membranes as disclosed in claims 1 and 10 of the instant invention.

Accordingly, Sluma in view of Otto do not disclose all of the elements of claim 10. Therefore, this rejection must fail.

Claims 12-20 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,906,375 (hereinafter Heilmann) in view of U.S. Patent No. 5,476,715 (hereinafter Otto) as further evidenced by U.S. Patent No. 5,290,448 (hereinafter Sluma). Applicant traverses.

As previously stated, in order to establish a prima facie case of obviousness under 35 U.S.C. §103(a), the reference or combination of references must teach or suggest all the elements of the claim (See MPEP 2143 above for the basic requirements of a prima facie case of obviousness). In this case, as shown below, Heilmann in view of Otto as further

evidenced by Sluma does not teach all the elements of claims 12-20.

The above comments regarding Heilmann, Otto, and Sluma are incorporated herein. As indicated by the Examiner, Heilmann does not disclose the incorporation of an interior filler containing a polyeletrolyte. The Examiner then attempts to rely on Otto as disclosing the incorporation of a polyelectrolyte with negative fixed charges into the interior filler. Again, the Examiner's reliance on Otto is misplaced.

Otto does not relate in any way to membranes, let alone to the separation characteristics of semipermeable membranes as disclosed in claim 12 of the instant invention. No hint can be found in Otto which discloses any manner of modifying the method disclosed in Heilmann in order to obtain membranes with improved separation characteristics. Otto discloses absorbent materials in particle form and methods related to modifying a particulate carrier with specific spacer molecules carrying ligands. Additionally, Otto does not teach or even hint as to any way to modify a membrane manufacturing process in order to improve the separation characteristics of the resulting membrane. Moreover, no hint can be taken from Otto that by adding a polyelectrolyte with negative fixed charges to the interior filler, which is extruded through the central opening of the hollow fiber die to stabilized the lumen of the

hollow fiber and which acts as a coagulant for the polymer and is causal for the development of a separating layer on the inner surface of the hollow fiber, will have any result on the separation characteristic of the resulting membrane. Otto discloses the use of absorbent materials in particle form whereby the particles have a size in the range of 50 to 250 µm and having spacers covalently bonded to the particles and organic ligands covalently bonded to the spacers. (Otto, Column 4, Lines 27-47). It would be nearly impossible to introduce these particles into the inner filler used in the method disclosed in claim 12 of the instant invention for manufacturing hollow fiber membranes having an internal diameter of 216 µm (Sluma, Column 4, Lines 15-17).

Accordingly, Heilmann in view of Sluma as further evidenced by Otto do not disclose all of the elements of claim 12. Therefore, this rejection must fail.

In reference to claims 13-20, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); In re Abele, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also In re Sernaker, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 13-20

are not unpatentable over Heilmann in view of Otto as further evidenced by Sluma and should be allowed.

No new matter has been added.

Conclusion

In view of the foregoing, Applicant respectfully requests an early Notice of Allowance in this application.

Respectfully submitted,

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